UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JUDY WETHINGTON, *et al.*,	:	
	:	Case No. 1:01cv441
Plaintiffs,	:	
	:	Judge S. Arthur Spiegel
v.	:	
	:	
PURDUE PHARMA, L.P., *et al.*,	:	
	:	
Defendants.	:	

PURDUE DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO RECONSIDER ORDER DENYING CLASS CERTIFICATION

PRELIMINARY STATEMENT

Unhappy with the October 1, 2003 Order denying class certification (the "October 1, 2003 Order") Plaintiffs move the Court for reconsideration. Motions to reconsider, however, are highly disfavored and should only be granted in an extraordinary circumstance. Here, no such circumstance exists. Plaintiffs' motion should be denied.

There are several reasons why this is so. First, as a threshold matter Plaintiffs' motion is untimely: it was due to be filed no later than ten days after entry of the October 1, 2003 Order, but instead was not filed until two weeks after that deadline had expired. Second, even without that defect, the motion does not establish the criteria upon which courts reconsider rulings regarding the propriety of class certification. There has not been any change in the applicable substantive or procedural law, nor is the October 1, 2003 Order unsound for any reason. In fact, the materials and arguments Plaintiffs filed with their reconsideration motion had already been *submitted to the Court prior to the October 1, 2003 Order* and, in any event, constitute nothing more than inaccurate, unverified and scientifically unsupported hearsay

allegations from a disgruntled former employee. Accordingly, there is no basis to grant Plaintiffs the relief they seek here. See e.g. Alba Conte & Herbert Newberg, Newberg on Class Actions, § 7:47 (4th ed. 2002) ("[i]n the absence of materially changed or clarified circumstances, or the occurrence of a condition on which the initial class ruling was expressly contingent, *courts should not condone a series of reargruments on the class issues by either the proponent or the opponent of [the] class, in the guise of motions to reconsider the class ruling*.") (emphasis supplied.)

Foregoing Sixth Circuit review of the October 1, 2003 Order, Plaintiffs instead filed this motion. Defendants assume Plaintiffs did so because the October 1, 2003 Order is entirely consistent with controlling authority. In re American Med. Sys. Inc., 75 F.3d 1069 (6th Cir. 1996). Additionally, this Court's decision is entirely consistent with (a) the abundant federal precedent denying class certification in personal-injury pharmaceutical products-liability litigations where resolution of liability hinges on patient-by-patient considerations inherently attendant to each individual patient's use of a prescription medication, and (b) the seven other OxyContin cases in which class certification has been denied or abandoned by plaintiffs and their counsel.[1] This Court properly recognized that the causation analysis/determination of *whether* a particular patient/plaintiff was "harmed" by his or her course of treatment with OxyContin would

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[1] See e.g. Harris v. Purdue Pharma L.P., 2003 WL 22669248 (S.D. Ohio Sept. 30, 2003); Gevedon v. Purdue Pharma L.P., 212 F.R.D. 333 (E.D. Ky. 2002); Foister v. Purdue Pharma, L.P., 2002 WL 1008608 (E.D. Ky. Feb. 26, 2002); Baker v. Purdue Pharma L.P., Civil Action No. 1:01-0553 (S.D. W. Va. Mar. 31, 2003); Roberts v. Purdue Pharma, L.P., C.A.1:01-3110-22 (D.S.C. Oct. 10, 2002); McCauley v. Purdue Pharma, L.P., Case No. 2:01CV00080 (W.D. Va. Mar. 14, 2002); Salisbury v. Purdue Pharma L.P., Case No. 01-241-KKC (E.D. Ky. Jan. 9, 2003). The lone decision to the contrary has been accepted for review by The Supreme Court of Ohio. Howland v. Purdue Pharma, L.P., Case No. 03-1538, Supreme Court of Ohio (Nov. 26, 2003).

rest on resolution of a host of individual factors unique to each patient's particular circumstances. (See Order p. 22-23.) The Court also properly found that Plaintiffs had failed to identify a single issue whose resolution would *materially advance the litigation* of a class' claims as Rule 23 requires. And in any event, the highly individualized claims and circumstances of each particular patient would predominate over any purported "common issue" even if Plaintiffs had been able to identify one. Plaintiffs simply re-hash old arguments. They offer nothing in their motion to reconsider that alters in any way this Court's sound analysis, reasoning and conclusions, and Plaintiffs' motion should thus be denied.

COUNTERSTATEMENT OF FACTS

Plaintiffs base their motion on four exhibits: the January 2003 FDA Warning Letter, a July 2001 FDA Talk Paper, the unverified Complaint of Marek Zakrzewski, and an October 2003 DEA document titled OxyContin Diversion and Abuse (exhibits D, E, B and C, respectively to Plaintiffs' motion). But Plaintiffs submitted to this Court the first three *prior* to the October 1, 2003 Order, and thus they cannot now support Plaintiffs' motion. The fourth concerns the very drug abusers Plaintiffs' counsel so strenuously maintained they do not represent. None of these materials supports Plaintiffs' bid for a second-bite at the class certification apple.

1. Plaintiffs Previously Submitted the January 2003 FDA Warning Letter and July 2001 FDA Talk Paper

Plaintiffs submitted, featured prominently, and discussed at length in their April 14, 2003 reply papers (see Exhibits K and L, and Memorandum of Law in Support of Plaintiffs' Reply Memorandum in Response to Purdue and Abbott Defendants' Opposition to Plaintiffs' Motion for Class Certification) the January 2003 FDA Warning Letter and the July 2001 FDA

Talk Paper. Purdue responded to, and refuted, those arguments in its May 14, 2003 Sur-Reply in Further Opposition to Plaintiffs' Amended Motion for Class Certification (see pp. 3-7, and n. 5).

2. Plaintiffs Improperly Premise their Reconsideration Motion on Marek Zakrzewski's Previously-Submitted, Scientifically Unfounded Allegations

Plaintiffs have also re-submitted the unsworn, unverified hearsay allegations of a disgruntled former employee (Marek Zakrzewski) who has commenced an employment discrimination lawsuit against Purdue. They had previously done so in early September, well before the October 1, 2003 ruling.

Even if the Zakrzewski complaint was new, admissible, factual evidence, his allegations simply do not raise a patient safety issue. As set forth in the Affidavit of Glenn Van Buskirk, Ph.D., sworn to December 3, 2003 and attached hereto, none of the issues Zakrzewski discusses in his discrimination complaint has anything to do with the safety of OxyContin Tablets. Zakrzewski's unsworn allegations relate to the unformulated raw materials (oxycodone hydrochloride and stearyl alcohol) and not to the finished OxyContin product. As explained in the Van Buskirk Affidavit, such allegations are of no moment because any purportedly unacceptable variations in those raw materials would be eliminated during processing.

And as further discussed in the Van Buskirk Affidavit, as well as in the declaration of Purdue Executive Dr. Paul Goldenheim previously filed by Purdue (see Declaration of Paul D. Goldenheim, M.D., sworn to March 21, 2003 (submitted with Purdue Defendants' Opposition to Plaintiffs' Amended Motion for Class Certification) ("Goldenheim Decl.")), Purdue's clinical data demonstrates to FDA's satisfaction that OxyContin is safe and effective. The development and manufacture of OxyContin is extensively regulated by the FDA, and has been since before OxyContin was ever introduced into the market. Before Purdue ever

launched OxyContin, it conducted several clinical studies in humans to test the safety and efficacy of the medication. Those clinical studies demonstrated the safety and efficacy of the medication, and FDA approved the medication based on those studies, finding then as it continues to find today, that OxyContin is "safe and effective" for the treatment of moderate to severe pain when used in accordance with the approved product labeling. In addition, since the date Purdue first began to market and sell OxyContin, Purdue has always conducted the tests required by FDA to ensure that the medication continues to meet all safety requirements, and always makes the necessary disclosures to FDA.

The Zakrzewski complaint is silent on any of these clinical studies and tests, and necessarily so, since Zakrzewski was not involved in any of Purdue's clinical trials. All of the testing Purdue continues to conduct on the finished OxyContin Tablets is done at facilities different from the facility where Zakrzewski worked, and Zakrzewski was never involved in any of that testing. Zakrzewski's claims regarding laboratory testing of a raw material simply are not relevant to whether the finished OxyContin Tablet raises patient safety issues.

3. The DEA Material Submitted by Plaintiffs Concerns Stopping the ***Abuse*** of OxyContin by Those Who Use it as a Street-Drug -- the Very People Whom Plaintiffs' Counsel Have Insisted They Do Not Seek to Represent in this Action

Plaintiffs refer to an October 2003 DEA document, titled OxyContin Diversion and Abuse, in which the DEA discusses ***drug abusers*** and the "*Non-Medical Use of OxyContin*." Indeed, the entire document is dedicated to describing how the DEA intends to combat drug abuse and drug diversion associated with OxyContin -- efforts in which Purdue has gone to great lengths to assist government and regulatory officials while still safe-guarding the interests of legitimate patients who benefit tremendously from opioid pain medications. (See Goldenheim Decl. at ¶¶ 52-63.) Contrary to Plaintiffs' misrepresentations, the October 2003 DEA document

does not state "OxyContin is highly addictive" -- rather, it discusses how OxyContin *can* be "highly addictive" to *abusers* who "compromise the controlled-release formulation for a powerful morphine-like high."[2] The document further discusses proposed DEA operations to:

- "target individuals and organizations involved in the ***diversion and abuse*** of OxyContin"; and to
- pursue "action that will make it more difficult for ***abusers*** to obtain OxyContin."

(Pls. Mem. Exh. C, pp. 7, 8.) (Emphasis supplied.) In fact, the October 2003 DEA document specifically recognizes that OxyContin is "***legitimately*** used as a medication to treat moderate to severe pain." (Id. at p. 1.) (Emphasis supplied.) Hence, the entire document is about stopping *drug abusers* -- the very people Plaintiffs steadfastly maintained were not represented in this action.

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[2] Plaintiffs also affirmatively misrepresent Dr. Goldenheim's testimony concerning whether OxyContin "is addictive." (Pls.' Mem. p. 4.) Dr. Goldenheim testified that addiction to opioid analgesics (of which OxyContin is one) arising de novo in the ordinary course of medical treatment *is rare* in a patient without a previous history of substance abuse. (Goldenheim Decl. at ¶ 36.) Additionally, the OxyContin product information (Goldenheim Decl. at Exhs. 8 through 17) has always disclosed and discussed the possibility of addiction when engaging in a course of opioid therapy. Indeed, this Court recognized at pages 27-28 of the October 1, 2003 Order that:

> "There is no question that OxyContin, like many other powerful prescription drugs, can be dangerous when it is not used as directed, or when it makes it to the street. Testimony before Congress, on behalf of the FDA, however, indicates that the benefits of the drug outweighed its risks when used according to the approved labeling, and that the FDA believes the drug is a valuable product for the treatment of moderate to severe pain when properly used."

ARGUMENT

A. Plaintiffs' Motion Is Untimely and Should Be Denied

As a threshold matter, Plaintiffs' motion seeking reconsideration of the October 1, 2003 Order is untimely. It is well-settled in this Circuit that district courts interpret motions to reconsider dispositive pretrial orders as Rule 59(e) motions to alter or amend the judgment.[3] See e.g. McDowell v. Dynamics Corp. of Am., 931 F.2d 380, 382 (6th Cir. 1991); Feathers v. Chevron U.S.A. Inc., 141 F.3d 264, 268 (6th Cir. 1998). A Rule 59(e) motion must be filed "no later than 10 days after entry of the judgment." FRCP 59(e); see e.g. Tregenza v. Great Am. Communications Co., 823 F. Supp. 1409, 1412 (N.D. Ill. 1993) ("[t]o the extent either party desires a reconsideration on class certification … a motion must be filed within 10 days, under Fed.R.Civ.P. 59(e)."). In this case, the ten days after entry of the October 1, 2003 Order expired on October 16, 2003[4] -- some two weeks prior to Plaintiffs filing the instant motion. Accordingly, the motion was filed out of time and should be denied.

B. The Timeliness Defect Aside, Plaintiffs Have Failed To Establish Any Basis to Warrant Reconsideration of the October 1, 2003 Order

Recognizing the untimeliness of their motion, Plaintiffs have improperly attempted to avoid any mention of Rule 59(e) and instead have asserted that their reconsideration request, made one month after the decision was issued, falls under the ambit of Rule 23(c)(1).

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[3] A "motion to reconsider" is found nowhere in the Federal Rules of Civil Procedure, nor in this district's local rules. (Some district court's local rules do provide for motions to reconsider. See e.g., Local Rule 7.1(g)(3) of the United States District Court for the Eastern District of Michigan which provides that motions for reconsideration must be filed within ten days of entry of the subject order.)

[4] Pursuant to FRCP 6(a), intervening Saturdays, Sundays and Columbus Day were not included in the ten day calculation.

That effort is unavailing and should be rejected. Rule 23(c)(1) does not allow parties to take an immediate second bite at the same class certification apple, nor does it permit parties -- who have not prevailed as they would have wished -- to petition the Court to *withdraw* the opinion. Irrespective of whether it is Rule 59(e) or Rule 23(c)(1) which applies, however, Plaintiffs have failed to establish the requisite standard for reconsideration.

Timely-filed Rule 59(e) "[m]otions to alter or amend judgment may be granted if there is a clear error of law, newly discovered evidence, an intervening change in controlling law, or [] manifest injustice." GenCorp, Inc. v. Am. Intern. Underwriters, 178 F.3d 804, 834 (6th Cir. 1999) (internal citations omitted). To constitute "newly discovered evidence," the evidence must have been previously unavailable. Sault St. Marie Tribe of Chippewa Indians v. Engler, 146 F.3d 367, 374 (6th Cir. 1998). "Motions for reconsideration do not allow the losing party to 'repeat arguments previously considered and rejected, or to raise new legal theories that should have been raised earlier.'" Owner-Operator Independent Drivers Assn., Inc. v. Arctic Express, Inc., No. 97-CV-750, 2003 WL 22439878, at *3 (S.D. Ohio Oct. 22, 2003) (internal citations omitted). Courts do not look favorably on motions to reconsider:

> Although "motions to reconsider are not ill-founded step-children of the federal court's procedural arsenal," *they are "extraordinary in nature and, because they run contrary to notions of finality and repose, should be discouraged*." . . . It is not the function of a motion to reconsider either to renew arguments already considered and rejected by a court or "to proffer a new legal theory or new evidence to support a prior argument when the legal theory or argument could, with due diligence, have been discovered and offered during the initial consideration of the issue."

McConocha v. Blue Cross & Blue Shield Mutual of Ohio, 930 F. Supp. 1182, 1184 (N.D. Ohio 1996) (citations omitted) (emphasis added).

Similarly, Rule 23(c)(1) provides that a Court can alter or amend a class certification decision on limited occasions. These include instances where there has been change in the

parties, a change in the substantive or procedural law, or if the original judgment somehow appears unsound because of later events. See Fed. R. Civ. P. 23(c)(1) advisory committee note; David F. Herr, Manual for Complex Litigation, 30.18 (3d ed. 2003). No such occasion has arisen here. This Court's decision is not unsound for any reason (or owing to any recent events). Plaintiffs' proffered "material" is not new.[5] There has not been any change in the parties, nor has there been any change in the applicable substantive or procedural law. Not only is the motion for reconsideration based upon an unverified and erroneous complaint of a disgruntled employee -- whose claims are still in the infancy of his own litigation -- but far from establishing that they have "evidence" warranting reconsideration, Plaintiffs instead seek time to go off and conduct discovery on their unfounded supposition to determine *whether* they can in fact develop any evidence to support it. (See Pls' Mem. p. 9.) As the Van Buskirk affidavit demonstrates, they would not be able to do so in any event.

The dearth of legal authority in Plaintiffs' memorandum of law is no accident: it is an accurate reflection of the law because *there are no cases to support Plaintiffs' motion in this instance.* In fact, there are almost no instances where plaintiffs have successfully obtained reconsideration of a *denial* of class certification, and the few cases which report plaintiffs having done so have no applicability here. See e.g., Luedke v. Delta Air Lines, Inc., No. 92 Civ. 1778 (RPP), 1993 WL 313577, at *1 (S.D.N.Y. Aug. 10, 1993) (plaintiffs' motion to reconsider the denial of the class motion in order to permit plaintiffs to amend their proposed class definition

[5] As discussed above, the unverified complaint was previously submitted to the Court in early September 2003, and the FDA Warning Letter and Talk Paper were submitted to this Court last April. The only document not previously submitted is the October 2003 DEA document, but that document is inapposite because it concerns abusers who use OxyContin for non-medicinal purposes.

granted; but thereafter, the court denied certification a second time); Hernandez v. Vidmar Buick Co., 910 F. Supp. 422 (N.D. Ill. 1996), rev'd on other grounds, Gibson v. Bob Watson Chevrolet-Geo, Inc., 112 F.3d 283 (7th Cir. 1997) (court granted plaintiffs' motion to reconsider its denial of class certification due to a change in controlling procedural law).

Conversely, one case which is applicable is Martin v. Easton Publishing Co., 74 F.R.D. 439 (E.D. Pa. 1977). As in Wethington, the Martin plaintiffs filed a motion to reconsider a little over a month after the initial denial of their class certification application. The Martin plaintiffs argued that discovery was not complete and that the court had misapplied and misinterpreted case law. The Martin court rejected those arguments and noted that "it appear[ed] that the suggestion of the need for further discovery [was] an after-thought resulting from the plaintiff's loss of the class action motion." Id. at 441. The same is true here -- the Wethington Plaintiffs did not ask for discovery when they first submitted the Zakrzewski complaint to the Court in early September, nor did they ask for discovery when they submitted the FDA Warning Letter and FDA Talk Paper in April 2003. The instant motion is no more than the same type of "after-thought" that the Martin court properly rejected. As in Martin, this Court should do the same.

C. There is No Basis for Plaintiffs' Request that the Court Withdraw And Reconsider Its Decision On The Merits

Finally, research has not revealed, and Plaintiffs have not cited, any case in which a district court withdrew and/or reconsidered its class certification ruling based upon one party's claim that the court improperly considered the merits in reaching its decision. Indeed, Plaintiffs' request here is the height of irony considering the avalanche of merits-based information and arguments they submitted to the Court in support of their amended motion for class certification. This Court properly addressed both the applicable law on a variety of points raised by the parties

(e.g. the doctrine of intentional product misuse, the Learned Intermediary doctrine), and the validity of the factual assertions which *Plaintiffs raised* in their failed effort to identify a Rule 23 "common" issue. In sum, the Court did what it was supposed to do. See e.g., Szabo v. Bridgeport Machs., Inc., 249 F.3d 672, 678 (7th Cir. 2001), cert. denied, 534 U.S. 951 (2001) (courts must look beyond the pleadings to the proof that will be necessary at trial in order to properly evaluate a motion to certify). Its analysis and reasoning was sound. Plaintiffs' motion should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 4, 2003, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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